STATEMENT

**BY APPLICANT** 

Docket: 4239-61725

Filed: April 30, 2001

App: 09/830,748

Applicant: Kashmiri et al.

Art Unit: Not yet assigned

\_\_\_\_

**U.S. PATENT DOCUMENTS** 

Init.*	Number	Date	Name	Class	Sub	Filed
100	4,816,567	3/28/89	Cabilly et al.		-7	
(	5,472,693	12/5/95	Gourlie et al.	1	)	
	5,482,040	1/9/96	Martin, Jr.		HOH	<b>50</b>
	5,512,443	4/30/96	Schlom et al.		OCT CEN	0
	5,534,254	7/9/96	Huston et al.		3 O	m
	5,585,089	12/17/96	Queen et al.		2002	m
	5,688,657	11/18/97	Tsang et al.		2900	
V	5,976,531	11/2/99	Mezes et al.		M	
M	5,976,845	11/2/99	Mezes et al.	_	-	
	T1	C DATERNIT A	DDI ICATION DOCUMENT		<del></del>	

## U.S. PATENT APPLICATION DOCUMENTS

₩ 08/961,309 10/30/97 Mezes et al.

## FOREIGN PATENT DOCUMENTS

N	Number	Date	Country	Class	Sub	
C	2,131,355	4/17/01	Canada	1		
	EP0239400 ×	9/30/87	ЕРО		1	
	EP0365997 🗴	5/2/90	EPO			
V	WO 89/00692	1/26/89	WIPO	16	1	
72	WO 89/01783	3/9/89	WIPO			

EXAMINER:

DATE 5/1/03

\*Examiner: Initial if considered, whether or not in conformance with MPEP 609; draw line through cite if not in conformance and not considered. Send copy.

\*Examiner: Initial if considered, whether or not in conformance with MPEP 609; draw line through cite if not in conformance and not considered. Send copy.

DATE

**EXAMINER:** 

## **HEUCIVED**

OCT 3 0 2002

OF TO		CH (Laby Exertion 2320) 1725	App: 09/830,748				
ان بر م	ORMATION DISCLOSURE STATEMENT	Applicant: Kashmiri et al	l.				
AUG 1 9 2002	BY APPLICANT	Filed: April 30, 2001	Art Unit: Not yet assigned				
LAA		e Complementarity-determining a Mouse," <i>Nature</i> <b>321</b> :522-525					
		n, Characterization, and <i>in Vive</i> CC49," <i>Hybridoma</i> <b>14(5)</b> :461-4					
Mulligan et al., "Phase I Study of Intravenous 177 Lu-labeled CC49 Murine Moderation Antibody in Patients with Advanced Adenocarcinoma," Clinical Cancer Research 1:1447-1454, December 1995.  Muraro et al., "Generation and Characterization of B72.3 Second Generation Monoclonal Antibodies Reactive with the Tumor-associated Glycoprotein 72 Antigen," Cancer Research 48:4588-4596, August 15, 1988.  Padlan et al., "Identification of Specificity-determining Residues in Antibodies FASEB Journal 9:133-139, January 1995.							
				Padlan, "A Possible Procedure for Reducing the Immunoger Domains while Preserving their Ligand-binding Properties," 28(4/5):489-498, 1991.			genicity of Antibody Variable s," <i>Molecular Immunology</i>
						Use of a H Chain V Region in A hal Antibodies," <i>The Journal of</i>	
		Grafted Antibody that Recogn Biotherapy 9(4):341-349, 1994					
Cer		logical Properties of Chimeric bulins," <i>Cancer Research (Sup</i>					
Op	Specificity-determining Re	rural Correlates of an Anticarcinoma Antibody: Identification of ang Residues (SDRs) and Development of a Minimally dy Variant by Retention of SDRs Only," <i>Journal of Immunology</i> ebruary 1, 2000.					
EXAMINE		DATE 5/1/03					
	Initial if considered, whether or not rmance and not considered. Send co		9; draw line through cite if				

MEULIVE-

OCT 3 0 2002

SAS:tjj 08/15/2002 4239-61725 E-258-98/2 Docket: 4239-61725 App: 09/830,748 RMATION DISCLOSURE Applicant: Kashmiri et al. **STATEMENT** AUG 1 9 2002 BY APPLICANT Filed: April 30, 2001 Art Unit: Not yet assigned TE TANK Xiang et al., "Complementarity Determining Region Residues Aspartic Acid at H55, Serine at H95 and Tyrosines at H97 and L96 Play Important Roles in the B72.3 10 Antibody-TAG72 Antigen Interaction," Protein Engineering 9(6):539-543, June 1996. Xiang et al., "The Tyrosine Residue at Position 97 in the V<sub>H</sub> CDR3 Region of a LP Mouse/Human Chimeric Anti-Colorectal Carcinoma Antibody Contributes Hydrogen Bonding to the TAG72 Antigen," Cancer Biotherapy 8(3):253-262, 1993. **EXAMINER: DATE** \*Examiner: Initial if considered, whether or not in conformance with MPEP 609; draw line through cite if not in conformance and not considered. Send copy.

Sheet 1 of 2

RECEI

			- / /
FORM 1449*  O I P INFORMATION DISCLOSURE STATEMENT	Docket Number: 11613.32USWO	Application Number: DEC 1 09/830,748 TECH CENTER	0 200
IN AN APPLICATION	Applicant: KASHMIRI ET AL.	TECH CENTER	7 1600/2
SEP 0 4 2001 (Use several sheets if necessary)	Filing Date: 04/30/2001	Group Art Unit: UNKNOWN	

PADEMAR'S						PTTATLY	70#1
TOE MIN			U.S. PATENT DOCUMEN	TS			
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS		DATE OPRIATE
LAR	4,816,567	03/28/1989	Cabilly et al.	~	~		<del></del>
1	5,472,693	12/05/1995	Gourlie et al.	1	)	-	
	5,482,040	01/09/1996	Martin, Jr.				<del></del>
	5,512,443	04/30/1996	Schlom et al.				<del></del>
	5,534,254	07/09/1996	Huston et al.				<del></del>
V	5,585,089	12/17/1996	Queen et al.	V			
(JR)	5,688,657	11/18/1997	Tsang et al.		<u></u>		
		FC	DREIGN PATENT DOCUM	ENTS			
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSI	LATION
					1	YES	NO
M	2,131,355	03/02/1996	CA	-			
1	0 239 400	09/30/1987	EP	1	1		
	0 365 997	05/02/1990	ЕР				
	WO 89/00692	01/26/1989	PCT				
	WO 89/01783	03/09/1989	PCT				
	WO 90/04410	05/03/1990	PCT				
	WO 93/12231	06/24/1993	PCT	1 1			
	WO 96/13594	05/09/1996	PCT				
	WO 97/26010	07/24/1997	PCT				
	WO 98/18809	05/07/1998	PCT		)		
V	WO 99/43816	09/02/1999	PCT	4	/		
1	WO 00/26394	05/11/2000	PCT	_	_		
	ОТН	ER DOCUMEN	TS (Including Author, Title, D	ate, Pertinent Pag	es, Etc.)	<u>.                                    </u>	
104	Abergel, C. et al., "Crystallographic Studies and Primary Structure of the Antitumor Monoclonal CC49 Fab", PROTEINS: Structure, Function, and Genetics, Vol. 17, pp. 438-443 (1993).						
TOH	Colcher, D. et al., "Radioimmunolocalization of Human Carcinoma Xenografts with B72.3 Second Generation Monoclonal Antibodies", Cancer Research, Vol. 48, pp. 45974603 (August 15, 1988).						

EXAMINER	DATE CONSIDERED	5/1/03	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

Group Art Unit: UNKNOWN

	)		Sheet 2 of 2
FORM 1449* IN	FORMATION DISCLOSURE STATEMENT	Docket Number: 11613.32USWO	Application Number: 09/830,748
OIA	IN AN APPLICATION	Applicant: KASHMIRI ET	AL.
4.1	(Use several sheets if necessary)	Filing Date: 04/30/2001	Group Art Unit: UNKNOWN

Filing Date: 04/30/2001

2001 32	
PADEMARY	Divgi, C. et al., "Clinical Comparison of Radiolocalization of Two Monoclonal Antibodies (mAbs) Against the TAG-72 Antigen", Nucl. Med. Biol., Vol. 21, No. 1, pp. 9-15 (1994).
	Hand, P. et al., "Potential for Recombinant Immunoglobulin Constructs in the Management of Carcinoma", CANCER Supplement, Vol. 73, No. 3, pp. 1105-1113 (February 1, 1994).
	Iwahashi, M. et al., "CDR Substitutions of a Humanized Monoclonal Antibody (CC49): Contributions of Individual CDRs to Antigen Binding and Immunogenicity", <i>Molecular Immunology</i> , Vol. 36, pp. 1079-1091 (1999).
	Johnson, V. et al., "Analysis of a Human Tumor-Associated Glycoprotein (TAG-72) Identified by Monoclonal Antibody B72.3", CANCER RESEARCH, Vol. 46, pp. 850-857 (February 1986).
	Jones, P. et al., "Replacing the Complementarity-Determining Regions in a Human Antibody with those from a Mouse", <i>Nature</i> , Vol. 321, pp. 522-525 (May 29, 1986).
	Kashmiri, S. et al., "Generation, Characterization, and in Vivo Studies of Humanized Anticarcinoma Antibody CC49", Hybridoma, Vol. 14, No. 5, pp. 461-473 (1995).
	Mulligan, T. et al., "Phase I Study of Intravenous <sup>177</sup> Lu-labeled CC49 Murine Monoclonal Antibody in Patients with Advanced Adenocarcinoma", <i>Clinical Cancer Research</i> , Vol. 1, pp. 1447-1454 (December 1995).
	Muraro, R. et al., "Generation and Characterization of B72.3 Second Generation Monoclonal Antibodies Reactive with the Tumor-associated Glycoprotein 72 Antigen", Cancer Research, Vol. 48, pp. 4588-4596 (August 15, 1988).
	Padlan, E., "A Possible Procedure for Reducing the Immunogenicity of Antibody Variable Domains While Preserving Their Ligand-Binding Properties", <i>Molecular Immunology</i> , Vol. 28, No. 4/5, pp. 489-498 (1991).
	Padlan, E. et al., "Identification of Specificity-Determining Residues in Antibodies", Research Communications, Vol. 9, pp. 133-139 (January 1995).
	Rixon, M. et al., "Preferential Use of a H Chain V Region in Antitumor-Associated Glycoprotein-72 Monoclonal Antibodies", <i>The Journal of Immunology</i> , Vol. 151, No. 11, pp. 6559-6568 (December 1, 1993).
	Sequence Listing from PCT Application PCT/US99/25552, "Variants of Humanized Anti-Carcinoma Monoclonal Antibody CC49", 12 pages (Filed October 29, 1999).
	Sha, Y. et al., "A Heavy-Chain Grafted Antibody that Recognizes the Tumor-Associated TAG72 Antigen", Cancer Biotherapy, Vol. 9, No. 4, pp. 341-349 (Winter 1994).
	Slavin-Chiorini, D. et al., "Biological Properties of Chimeric Domain-deleted Anticarcinoma Immunoglobulins", Cancer Research (Suppl.), Vol. 55, pp. 5957s-5967s (December 1, 1995).
	Tamura, M. et al., "Structural Correlates of an Anticarcinoma Antibody: Identification of Specificity-Determining Residues (SDRs) and Development of a Minimally Immunogenic Antibody Variant by Retention of SDRs Only", <i>The Journal of Immunology</i> , Vol. 164, No. 3, pp. 1432-1441 (February 1, 2000).
4	Xiang, J. et al., "Complementarity Determining Region Residues Aspartic Acid at H55, Serine at H95 and Tyrosines at H97 and L96 Play Important Roles in the B72.3 Antibody-TAG72 Antigen Interaction", <i>Protein Engineering</i> , Vol. 9, No. 6, pp. 539-543 (June 1996).
25	Xiang, J. et al., "The Tyrosine Residue at Position 97 in the V <sub>H</sub> CDR3 Region of a Mouse/Human Chimeric Anti-Colorectal Carcinoma Antibody Contributes Hydrogen Bonding to the TAG72 Antigen", Cancer Biotherapy, Vol. 8, No. 3, pp. 253-262 (Fall 1993).

23552

**EXAMINER** 

DATE CONSIDERED

PATENT TRADEMARK OFFICE

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.